

247 CMR 5.00: ORALLY AND ELECTRONICALLY TRANSMITTED PRESCRIPTIONS;
ELECTRONIC DATA TRANSMISSION SYSTEM.

Section

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5.01: Foreword

Except for the regulations pertaining to electronically transmitted prescriptions, the Department of Public Health and the Board of Registration in Pharmacy, acting jointly under authority of M.G.L. c. 94C, and every other act thereto enabling, and in accordance with the procedures set forth in M.G.L. c. 30A, hereby establish regulations for the implementation of M.G.L. c. 94C.

5.02: Electronically Transmitted Prescriptions

(1) Prescriptions or drug orders may be electronically transmitted from an authorized prescribing practitioner or his or her expressly authorized agent to a pharmacy or pharmacy department of the patient's choice. The prescription or drug order shall be electronically transmitted in a manner that maintains patient confidentiality and in accordance with the requirements of M.G.L. c. 94C, § 23(g) and 105 CMR 721.000 *et seq.*

(2) A pharmacist or pharmacy shall not enter into any agreement concerning the provision of a computer, facsimile machine, computer modem or any other electronic device which would adversely affect a patient's freedom to select the pharmacy or pharmacy department of his or her choice.

(3) A pharmacist or pharmacy shall not provide a computer, facsimile machine, computer modem or any other electronic device to a prescriber or health care facility for the purpose of providing an incentive to refer patients to a particular pharmacy or pharmacy department.

5.03: Emergency Situations in Which Controlled Substances in Schedule II May be Dispensed Upon Orally or Electronically Transmitted Prescription

(1) "Emergency situations", for the purpose of permitting the dispensing of any controlled substance in Schedule II upon orally or electronically transmitted prescription, means those situations in which the practitioner who intends to prescribe a controlled substance in Schedule II determines:

- (a) That the immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user;
- (b) that no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II; and
- (c) that it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the controlled substance prior to the dispensing.

(2) In case of an emergency situation as defined in 247 CMR 5.03(1), a pharmacist may dispense a controlled substance in Schedule II upon receiving the orally or electronically transmitted authorization of a prescribing practitioner, provided that:

- (a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.
- (b) the prescription contains all information required by M.G.L. c. 94C, § 20(a) except for the actual signature of the prescribing practitioner, and in the case of an oral prescription, or prescription transmitted electronically by computer modem or other similar electronic device, the prescription is immediately reduced to writing by the dispensing pharmacist; and

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(c) the dispensing pharmacist makes a reasonable good faith effort to determine that the orally or electronically transmitted authorization was issued by an authorized practitioner, which effort may include a callback to the prescribing practitioner or other good faith efforts to ensure the prescribing practitioner's identity.

(3) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the pharmacy which must have written on its face "Authorization for Emergency Dispensing" and should comply with federal and state law.

(4) Upon receipt of the written prescription, the dispensing pharmacist shall attach the prescription to the orally or electronically transmitted emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration, U.S. Department of Justice, and the Commissioner of Public Health, Massachusetts Department of Public Health, if the prescribing practitioner fails to deliver a written prescription within seven days.

5.04: Utilization of Electronic Data Transmission (EDT) System

247 CMR 5.04, in conjunction with regulations of the Department of Public Health at 105 CMR 700.006, are intended to address the problem of prescription drug abuse and diversion. By requiring the reporting of information relative to prescriptions for controlled substances in Schedule II, a more efficient means of monitoring distribution between the practitioner, dispenser, and patient is provided.

(1) Pharmacy Reporting Responsibilities.

(a) Every pharmacy registered by the Board and hospital pharmacy issued a controlled substances registration by the Board that dispenses controlled substances in Schedule II pursuant to a prescription shall transmit to the Department of Public Health or its agent the following information for each prescription:

1. Pharmacy prescription number;
2. pharmacy NABP Number;
3. patient identifier, where feasible;
4. date the controlled substance is dispensed;
5. metric quantity of controlled substance dispensed;
6. National Drug Code (NDC) Number of controlled substance dispensed;
7. estimated days supply of controlled substance dispensed; and
8. prescriber's U.S. Drug Enforcement Administration (DEA) controlled substance registration number.

(b) The pharmacist shall make a good faith effort to verify the patient identifier of the person to whom the prescription for a controlled substance in Schedule II is delivered in accordance with professional standards and personal judgment.

(c) The information required by 247 CMR 5.04 shall be transmitted to the Department of Public Health or its agent no later than 15 days following the last day of the month in which the prescription was dispensed by use of:

1. An electronic device, computer diskette, or magnetic tape, each of which shall be in a format approved by the Department, or other acceptable electronic method approved by the Department; or
2. a Universal Claim Form (UCF).

(d) Pharmacies reporting data from 25 or more prescriptions in any given month shall provide the required information in accordance with 247 CMR 5.04(1)(c)1..

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(2) Penalties. Failure to comply with the reporting requirements set forth in 247 CMR 5.04(1) and/or any state law or regulation relating to such reporting requirements may result in formal disciplinary action being initiated against the licensed pharmacist and/or the pharmacy by the Board and/or other state and federal law enforcement agencies.

REGULATORY AUTHORITY

247 CMR 5.00: M.G.L. c. 112, § 42A; c. 94C, § 6.

NON-TEXT PAGE